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Listed below are the item(s) being submitted with this Certificate of Transmission:\*\*

- 1) Appeal Brief (17 pages)
- 2) Fee Transmittal

Number of Pages Including this Page: 19

Inventor(s): Joseph R. Diehl et al.

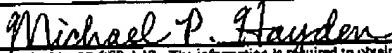
S.N.: 10/078,816

Filed: February 19, 2002

Docket #: 8868

<b>FEE TRANSMITTAL</b> <b>for FY 2005</b> Patent fees are subject to annual revision. Effective December 8, 2004		<b>Complete if Known</b>	
		Application Number	10/078,816
		Confirmation Number	7132
		Filing Date	19 February 2002
		First Named Inventor	Joseph R. Diehl
		Examiner Name	C. Lynne Anderson
Art Unit	3761		
<b>TOTAL AMOUNT OF PAYMENT (\$)</b>	<b>500</b>	Attorney Docket No.	<b>8868</b>

<b>METHOD OF PAYMENT</b>			<b>FEES CALCULATION (continued)</b>																																				
1. [X] The Director is hereby authorized to charge indicated fees submitted on this form, credit any over payments, and charge any additional fee(s) during the pendency of this application to: Deposit Account Number: 16-2480 Deposit Account Name: The Procter & Gamble Company			5. <b>ADDITIONAL FEES</b> <b>Fee Description</b> <span style="float: right;"><b>Fee Paid</b></span> Extension for reply within 1 <sup>st</sup> month (\$120) <input type="checkbox"/> Extension for reply within 2 <sup>nd</sup> month (\$450) <input type="checkbox"/> Extension for reply within 3 <sup>rd</sup> month (\$1,020) <input type="checkbox"/> Extension for reply within 4 <sup>th</sup> month (\$1,590) <input type="checkbox"/> Extension for reply within 5 <sup>th</sup> month (\$2,160) <input type="checkbox"/>  Information Disclosure Statement fee (\$180) <input type="checkbox"/>  37 CFR 1.16(f) Late Oath/Declaration (nonprovisional) (\$130) <input type="checkbox"/> 37 CFR 1.17 (g) Surcharge - Late provisional filing fee or cover sheet (\$50) <input type="checkbox"/> Non-English specification (\$130) <input type="checkbox"/>  Notice of Appeal (\$500) <input type="checkbox"/> Filing a brief in support of an appeal (\$500) \$500 Request for oral hearing (\$1,000) <input type="checkbox"/>  Acceptance of unintentionally delayed claim for priority under 35 U.S.C. 119, 120, 121, or 365 (a) or (c) (\$1,370) <input type="checkbox"/> Other: _____ <input type="checkbox"/>																																				
2. <b>BASIC FILING FEE - Large Entity</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">FILING</th> <th style="text-align: center;">SEARCH</th> <th style="text-align: center;">EXAMINATION</th> <th></th> </tr> <tr> <th></th> <th style="text-align: center;">FEE</th> <th style="text-align: center;">FEE</th> <th style="text-align: center;">FEE</th> <th></th> </tr> </thead> <tbody> <tr> <td><u>Application Type</u></td> <td></td> <td></td> <td></td> <td style="text-align: right;"><u>Fee Paid</u></td> </tr> <tr> <td>Utility</td> <td style="text-align: right;">(\$300)</td> <td style="text-align: right;">(\$500)</td> <td style="text-align: right;">(\$200)</td> <td style="text-align: right;">(Total = \$1000) <input type="checkbox"/></td> </tr> <tr> <td>Design</td> <td style="text-align: right;">(\$200)</td> <td style="text-align: right;">(\$100)</td> <td style="text-align: right;">(\$130)</td> <td style="text-align: right;">(Total = \$430) <input type="checkbox"/></td> </tr> <tr> <td>Reissue</td> <td style="text-align: right;">(\$300)</td> <td style="text-align: right;">(\$500)</td> <td style="text-align: right;">(\$600)</td> <td style="text-align: right;">(Total = \$1400) <input type="checkbox"/></td> </tr> <tr> <td>Provisional filing fee</td> <td></td> <td></td> <td></td> <td style="text-align: right;">(Total = \$200) <input type="checkbox"/></td> </tr> </tbody> </table>				FILING	SEARCH	EXAMINATION			FEE	FEE	FEE		<u>Application Type</u>				<u>Fee Paid</u>	Utility	(\$300)	(\$500)	(\$200)	(Total = \$1000) <input type="checkbox"/>	Design	(\$200)	(\$100)	(\$130)	(Total = \$430) <input type="checkbox"/>	Reissue	(\$300)	(\$500)	(\$600)	(Total = \$1400) <input type="checkbox"/>	Provisional filing fee				(Total = \$200) <input type="checkbox"/>		
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3. <b>APPLICATION SIZE FEE:</b> Sheets of Spec and Drawings <input type="checkbox"/> (\$250 for each 50 sheets in excess of 100, except for sequence and program listings) <b>SUBTOTAL (2)+(3) (\$)</b> <input type="checkbox"/>																																							
4. <b>EXTRA CLAIM FEES FOR UTILITY AND REISSUE:</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Extra Claims</th> <th style="text-align: center;">Fee from Below</th> <th style="text-align: center;">Fee Paid</th> </tr> </thead> <tbody> <tr> <td>Total Claims</td> <td style="text-align: right;">[ ] - 20** = [ ] x <input type="checkbox"/></td> <td style="text-align: right;">[ ] = <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Independent Claims</td> <td style="text-align: right;">[ ] - 3** = [ ] x <input type="checkbox"/></td> <td style="text-align: right;">[ ] = <input type="checkbox"/></td> <td></td> </tr> <tr> <td>Multiple Dependent claims:</td> <td style="text-align: right;">[ ] = <input type="checkbox"/></td> <td></td> <td></td> </tr> </tbody> </table> <p>** or number previously paid, if greater; For Reissues, see below</p> <p><b>Fee Description</b></p> <p>Claims in excess of 20 (\$50 per claim)          Independent claims in excess of 3 (\$200 per claim)          Multiple dependent claim, if not paid (\$360)          **Reissue: each independent claim over 3 and more than in the original patent (\$200 per claim)          **Reissue claims: each claim over 20 and more than original patent (\$50 per claim)</p> <p><b>SUBTOTAL (4) (\$)</b> <input type="checkbox"/></p>				Extra Claims	Fee from Below	Fee Paid	Total Claims	[ ] - 20** = [ ] x <input type="checkbox"/>	[ ] = <input type="checkbox"/>		Independent Claims	[ ] - 3** = [ ] x <input type="checkbox"/>	[ ] = <input type="checkbox"/>		Multiple Dependent claims:	[ ] = <input type="checkbox"/>			<b>SUBTOTAL(5) (\$)</b> <b>500</b>																				
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<b>SUBMITTED BY</b>		<b>Complete (if applicable)</b>		
Name (Print/Type)	Michael P. Hayden	Registration No. (Attorney/Agent)	48,433	Telephone (513) 634-5801
Signature	 <small>This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 15 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</small>			

+ This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 15 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Joseph R. Diehl *et al.*

Application No.: 10/078,816

Filed: 19 February 2002

Art Unit: 3761

Examiner: C. Lynne Anderson

Docket No.: 8868

Confirmation No.: 7132

Customer No.: 27752

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APR 13 2005

Title: Absorbent Article Having A Dehydration IndicatorAPPEAL BRIEF

Commissioner for Patents  
Alexandria, VA 22313-1450

Claims 1-20 in the subject Application were rejected for the second time in a Final Office Action mailed on 17 November 2004. An After Final Reply was timely submitted on 12 January 2005. A Notice of Appeal was timely filed on 17 February 2005. An Advisory Action was mailed on 22 February 2005, maintaining the rejections set forth in the aforementioned Final Office Action.

Real Party in Interest

The real party in interest is The Procter & Gamble Company, assignee of the entire interest.

Related Appeals and Interferences

No related appeal or interference is known to exist.

Status of Claims

Claims 1 through 20 remain pending and under final rejections that are the subject of this appeal.

Status of Amendments

The claims are in their original form, never having been amended. Amendments to the description and to a drawing to correct inadvertent errors, *i.e.*, amendments not affecting the claims, were included in the After Final Reply submitted on 12 January 2005 and their entry was

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requested in order to correct the text and the drawing for either allowance or appeal. However, it was indicated in the Advisory Action mailed on 22 February 2005 that these amendments would not be entered, without providing a reason for denying their entry.

#### SUMMARY OF CLAIMED SUBJECT MATTER

The independent claims are Claims 1, 10, and 17 and are directed to an article comprising a dehydration indicator, which is adapted to measure a urine ionic strength correlated to a specific gravity of the wearer's urine and to provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold value of the specific gravity.

In Claim 1, the wearable article 20 (page 2, lines 10-12 and 34; Figures 1, 9) comprises:

- a topsheet 24 (page 2, lines 36-37; Figures 1, 2A, 2B, 9), which is adapted to fit about a portion of a wearer (page 2, lines 10-14 and 28-33) and receive urine discharged by the wearer (page 2, lines 22-23; page 3, lines 24-25); and
- a dehydration indicator 60 (page 4, lines 3-5; Figures 1-9), which is disposed on and affixed to a component of the wearable article (page 7, lines 23-24) and is adapted to measure a urine ionic strength (page 4, lines 28-29) correlated to a specific gravity of the wearer's urine (page 4, lines 25-29) and provide a visible signal (page 4, line 30; page 6, line 2 through page 8, line 4) when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity (page 6, line 18 through page 8, line 4).

In Claim 10, the disposable absorbent article 20 (page 2, lines 28-29 and 34; Figures 1, 9) for receiving and containing bodily exudates including urine from a wearer (page 2, lines 22-23) comprises:

- an outer cover 26 (alternately designated as a "backsheets"; page 2, lines 22-23, page 7, lines 28-30; Figures 1, 2A, 2B, 9) adapted to fit about a portion of the wearer (page 2, lines 10-14 and 28-33);
- a fluid permeable topsheet 24 (page 2, lines 36-37; Figures 1, 2A, 2B, 9), onto and through which the urine is received (page 3, lines 24-25);

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- an absorbent structure 28 (page 2, lines 36-38; page 3, lines 26-34; Figures 1, 2A, 2B, 9) disposed adjacent at least a portion of the outer cover (page 2, lines 37-38; Figures 1, 2A, 2B, 9); and
- a dehydration indicator 60 (page 4, lines 3-5; Figures 1-9), which is adapted to measure a urine ionic strength (page 4, lines 28-29) correlated to a specific gravity of the wearer's urine (page 4, lines 25-29) and provide a visible signal (page 4, line 30; page 6, line 2 through page 8, line 4) when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity (page 6, line 18 through page 8, line 4).

In **Claim 17**, an insert (page 2, lines 17-19) for use with a wearable article 20 (page 2, lines 10-12 and 34; Figures 1, 9) comprises a dehydration indicator 60 (page 4, lines 3-5; Figures 1-9), which is adapted to measure a urine ionic strength (page 4, lines 28-29) correlated to a specific gravity of the wearer's urine (page 4, lines 25-29) and provide a visible signal (page 4, line 30; page 6, line 2 through page 8, line 4) when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity (page 6, line 18 through page 8, line 4).

**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

**Claims 1, 2, 4 through 12, and 14 through 20** stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,515,194 to Neading *et al.*

**Claims 3 and 13** stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5, 947,943 to Lee.

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### ARGUMENTS

#### Rejections of Claims 1, 2, 4 through 12, and 14 through 20 under 35 USC § 102(e)

These claims stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,515,194 to Neading *et al.*

It is noted that **Claims 2 through 9** depend from independent **Claim 1** and thereby include every limitation of **Claim 1**. Similarly, **Claims 11 through 16** depend from independent **Claim 10** and thereby include every limitation of **Claim 10**. Finally, **Claims 18 through 20** depend from independent **Claim 17** and thereby include every limitation of **Claim 17**.

According to the Manual of Patent Examining Procedure (MPEP) § 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

By this standard, the rejected claims have not been shown to be anticipated because, as explained below, it has not been shown that the cited reference teaches each and every element of any of the rejected claims.

#### Claims 1, 10, and 17

Each of the independent **Claims 1, 10, and 17** explicitly recites that the claimed dehydration indicator is “adapted to measure a urine ionic strength correlated to a specific gravity of the wearer’s urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity.” The Neading *et al.* reference fails to disclose at least the following elements of these claims.

#### The reference fails to disclose ionic strength or a measurement of urine ionic strength

The claimed dehydration indicator measures urine ionic strength. In contrast, as was expressly admitted in the Final Office Action (page 4, lines 21-22), “Neading does not explicitly disclose the measurement of urine ionic strength”. In fact, the cited Neading *et al.* reference fails to mention ionic strength.

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Instead, the rejections are based on the wetness indicator of the Neading *et al.* reference measuring the specific gravity of the urine and the fact that urine specific gravity can be correlated to urine ionic strength. However, the claim limitation is not that the dehydration indicator measures a property correlated to urine ionic strength. The claim limitation is that the dehydration indicator measures urine ionic strength. **Measuring urine specific gravity is not the same as measuring urine ionic strength.** Therefore, the claim limitation is not met by a device that measures urine specific gravity.

The reference fails to disclose a provision of a signal in response to urine ionic strength

The claimed dehydration indicator provides a visible signal when the urine ionic strength reaches a certain value. In contrast, the rejections are based on the Neading *et al.* reference providing a visible response in response to specific gravity. In fact, the cited Neading *et al.* reference fails to mention ionic strength. Moreover, the claim limitation is not that the dehydration indicator provides a visible signal in response to specific gravity or any other property that might be correlated to urine ionic strength. The claim limitation is that the dehydration indicator provides the visible signal when the urine ionic strength reaches a certain value. **Providing a visible response in response to urine specific gravity is not the same as providing a visible signal when the urine ionic strength reaches a certain value.** Therefore, the claim limitation is not met by a device that provides a visible response in response to urine specific gravity.

The reference fails to disclose a predetermined threshold of specific gravity

The claimed dehydration indicator provides a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity. The definition of "threshold" is "[t]he point that must be exceeded to begin producing a given effect or result or to elicit a response" (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000).

In contrast, as was expressly admitted in the Advisory Action (page 2, lines 10-11), the Neading *et al.* reference does not explicitly disclose a specific gravity threshold. In fact, the cited Neading *et al.* reference fails to mention any threshold of any property or parameter. Instead, the rejections are based on the conjecture that "a reagent chosen to change color to indicate a specific level of specific gravity would have a predetermined threshold (i.e. the

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specific gravity at which the color change is elicited)" (Advisory Action, page 2, lines 9-10). However, the conjectured reagent is not found, either expressly or inherently described, in the cited reference. In fact, the Neading *et al.* reference fails to disclose any predetermination of a threshold of specific gravity or even any method of measuring specific gravity. Instead, specific gravity is merely listed along with twenty other potential elicitors of a visible response, ranging from "wetness" to "temperature" to "bilirubin", etc. Therefore, the present claim limitation regarding the predetermined threshold of the specific gravity is not met by the Neading *et al.* reference.

**Claims 2, 4 through 9, 11, 12, 14 through 16, and 18 through 20**

As noted above, these claims depend from and thereby contain all the limitations of independent Claims 1, 10, and 17. Therefore, the failure of the Neading *et al.* reference to teach each and every element of any of independent Claims 1, 10, and 17 precludes its anticipation of any of these dependent claims, as well.

**Claims 8 and 14**

In addition to the previously identified unmet limitations of independent Claims 1 and 17, from which they respectively depend, each of Claims 8 and 14 contains the limitation that "the dehydration indicator is covered by a semipermeable membrane".

In the Final Office Action, it was alleged that element 14B of the Neading *et al.* reference is a semipermeable membrane (Final Action, page 3, lines 9-10). The element 14B is explicitly disclosed in the Neading *et al.* reference to be the "centrally-located portion 14B of the fluid transport layer 14" (column 2, lines 60-61), which is either "disposed between the inner layer 18 and the absorbent layer 20...disposed between the absorbent layer 20 and the outer layer 22...[or]...incorporated with the inner layer 18 or the absorbent layer 20" (column 3, lines 24-30).

Then, in the Advisory Action, in response to arguments presented in the Reply to the Final Office Action, it was alleged that the "topsheet" of the Neading *et al.* reference "fulfills the limitation of being semipermeable" (Advisory Action, page 2, lines 18-19). This reference to a "topsheet" in the Advisory Action fails to identify any specific structural element, because the Neading *et al.*

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reference does not include the term "topsheet". It is presumed that it was intended to refer to a structural analogue to the topsheet of the present invention. The only layer in the diaper 10 of the Neading *et al.* reference that overlies the other layers and contacts the skin of the wearer, like the topsheet of the present invention, is the inner layer 18.

Thus, the rejections are based on either the centrally-located portion 14B of the fluid transport layer 14 or the inner layer 18 being a semipermeable membrane. However, neither of these layers is disclosed in the Neading *et al.* reference to be a semipermeable membrane. In fact, the Neading *et al.* reference fails to mention a semipermeable membrane or anything that falls within the definition of the term.

The meaning of the term "semipermeable membrane" is well-known in the art. Representative examples of its definition and usage include the following.

semipermeable: Allowing passage of certain, especially small, molecules or ions but acting as a barrier to others. Used of biological and synthetic membranes.

The American Heritage® Dictionary of the English Language: Fourth Edition.  
2000

membrane: *Chemistry* A thin sheet of natural or synthetic material that is permeable to substances in solution.

The American Heritage® Dictionary of the English Language: Fourth Edition.  
2000

semipermeable membrane - A membrane that permits the passage of a solvent, such as water, but prevents the passage of the dissolved substance, or solute.

Glossary of Terminology, Nephrogenic Diabetes Insipidus Foundation at:  
<http://www.ndif.org/Terms/membrane.html>

A semipermeable membrane is one through which the molecules of a solvent can pass but the molecules of most solutes cannot.

Terminology Reference System, U.S. Environmental Protection Agency at:  
[http://oaspub.epa.gov/trs/trs\\_proc\\_qry.navigate\\_term?p\\_term\\_id=30127&p\\_term\\_cd=TERMDIS](http://oaspub.epa.gov/trs/trs_proc_qry.navigate_term?p_term_id=30127&p_term_cd=TERMDIS)

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Osmosis: transfer of a liquid solvent through a semipermeable membrane that does not allow dissolved solids (solutes) to pass.

The Columbia Encyclopedia, Sixth Edition, 2001, at:

<http://www.bartleby.com/65/os/osmosis.html>

Osmosis: the spontaneous passage or diffusion of water or other solvents through a semipermeable membrane (one that blocks the passage of dissolved substances—*i.e.*, solutes).

Encyclopædia Britannica Online at:

<http://www.britannica.com/eb/article?tocId=9057559&query=semipermeable&ct=eb>

In addition, the special distinction of a semipermeable membrane is well-known in the art and it is likewise well-known that manufactured semipermeable membranes are commonly used in water filtration, dialysis, reverse osmosis, and other processes.

Furthermore, exemplary materials are listed in the present Application on page 8 at lines 26-28, where it is recited that “[s]uitable exemplary semipermeable membranes include cellulose acetate, cellulose diacetate, cellulose triacetate, agar acetate, beta glucan acetate, polymeric epoxides, semipermeable polyurethanes, and semipermeable polyglycolic acid.”

In contrast, as previously mentioned, the Neading *et al.* reference fails to mention a semipermeable membrane or anything that falls within the definition of the term. In particular, the fluid transport layer 14 whose centrally-located portion 14B was alleged in the Final Office Action to be a semipermeable membrane is explicitly disclosed in the Neading *et al.* reference to be “made of any suitable hydrophilic material capable of creating...wicking or capillary action...[and]...may be composed of cellulose paper, hydrophilic polyester, nitrocellulose, rayon fiber, nylon fiber, silica gel, filter paper or the like” (column 3, lines 40-44). Clearly, this description of the fluid transport layer 14 does not include a semipermeable membrane.

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Similarly, the inner layer 18, which was apparently identified by the reference to a "topsheet" in the Advisory Action, is explicitly disclosed to be "comprised of a substantially fluid-permeable material of any suitable type" (column 3, lines 11-12) and it is further explicitly disclosed that "the materials of the inner, absorbent and outer layers 18, 20, 22 can be the same as those comparable layers found in existing commercially-available diapers" (column 3, lines 16-19). Clearly, this description of the inner layer 18 does not include a semipermeable membrane. Specifically, as is well-known in the art, semipermeable membranes are not commonly used as topsheets "in existing commercially-available diapers".

Summary with respect to rejections of Claims 1, 2, 4 through 12, and 14 through 20

The cited reference fails to teach each and every element of the independent **Claims 1, 10, and 17** and thereby likewise fails to teach each and every element of the dependent claims. Additionally, the cited reference fails to teach the additional element in **Claims 8 and 14**.

Rejections of Claims 3 and 13 under 35 USC § 103(a)

These claims stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,515,194 to Neading *et al.* in view of U.S. Patent No. 5, 947,943 to Lee.

It is noted that **Claims 3 and 13** respectively depend from independent **Claims 1 and 10** and thereby include every limitation of **Claims 1 and 10**.

According to MPEP § 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

By this standard, a *prima facie* case of obviousness has not been established, for at least the following reasons.

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All the claim limitations are not taught or suggested

Claims 3 and 13 respectively depend from independent Claims 1 and 10 and thereby contain the limitations that the claimed dehydration indicator is “adapted to measure a urine ionic strength correlated to a specific gravity of the wearer’s urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity.”

On the other hand, as discussed above with respect to the rejections under 35 USC § 102(e), the cited Neading *et al.* reference fails to disclose ionic strength or a measurement of urine ionic strength, fails to disclose a provision of a signal in response to urine ionic strength, and fails to disclose a predetermined threshold of specific gravity. The cited Lee reference likewise fails to disclose any of these elements and therefore fails to remedy the shortcomings of the Neading *et al.* reference.

Therefore, the cited references, either when taken alone or in combination, fail to teach or suggest all of the limitations of Claims 3 and 13.

There is no suggestion or motivation to modify or to combine reference teachings

Each of Claims 3 and 13 contains the limitation that the dehydration indicator is covered by a translucent cover. The cited references contain no suggestion or motivation to modify the article of the Neading *et al.* reference to make a layer translucent as proposed in the rejections and, in fact, teach away from such a modification.

It was stated in the Final Office Action that “Neading...remains silent with respect to the outer cover [layer] 22...The outer cover 16 of the article [of Lee] is translucent so the indicator may be easily viewed without removing the article. It would therefore be obvious to...make the outer cover of Neading translucent, as taught by Lee, so the indicator may be easily viewed without removing the article” (Final Action, page 3, last two lines through page 4, line 7). It was also stated in the Final Office Action that this modification “would allow the entire article of Neading to be covered by the backsheet while the indicator remains visible. Thus, Lee teaches an improvement to Neading” (Final Action, page 5, lines 16-18). Then, in the Advisory Action, it was alleged that “figures 6 and 7 of Neading show the indicator within the boundaries of, and

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therefore covered by, the article 12, thus creating a need for a translucent cover through which the indicator may be seen" (Advisory Action, page 2, lines 21-23).

However, this characterization of the disclosures of the cited references is inaccurate because no modification is necessary for the indicator of Neading et al. to be seen. Instead, the wetness indicator 16 of Neading et al. is explicitly disclosed to be exposed, i.e., not covered by any other layer, and therefore visible at the peripheral edge 14A (column 2, lines 4 and 56; column 3, line 62; column 4, lines 45, 49, and 67; column 5, line 23; column 6, lines 6, 17, 23, and 29; Figures 1, 3, 5, 6, and 7). In every embodiment disclosed in the Neading et al. reference, the visible response at "the peripheral edge 14A provides an immediate indicator visible to the person caring for the small child that the child has excreted waste and soiled the diaper and that the diaper 10 should now be replaced with a fresh one" (column 4, lines 27-31; underlining added).

Specifically, in a "first embodiment, the peripheral edge 14A which contains the wetness indicator 16...is exposed and visible along the ends and sides of the peripheral edge 12A of the diaper substrate 12 such that the peripheral edge 14A both lines and protrudes from the perimeter or peripheral edge 12A...Thus, the visible response of the wetness indicator 16 can be visible along substantially all portions of the peripheral edge 12A" (column 3, line 58 through column 4, line 1; underlining added).

Similarly, in a second embodiment shown in Figures 4 and 5, "the peripheral edge 14A of the transport layer 14 containing the wetness indicator 16 is exposed along at least one or both of the opposite front and rear portions 12C, 12D of the diaper substrate such that the visible response of the wetness indicator 16 can be visible along the at least one or both of the opposite front and rear portions 12C, 12D of the peripheral edge 12A of the diaper substrate 12" (column 4, lines 43-49; underlining added).

Likewise, in a third embodiment shown in Figure 6, "the peripheral edge 14A of the transport layer 14 containing the wetness indicator 16 is exposed along at least one or both of the opposite side portions 12E, 12F of the diaper substrate 12. Thus, the visible response of the wetness indicator 16 can be visible along the at least one or both of the opposite side portions 12E, 12F of the peripheral edge 12A of the diaper substrate 12" (column 4, lines 56-59; underlining

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added). It is particularly noted that this embodiment was mischaracterized in the Advisory Action, where it was misstated that "figures 6 and 7 of Neading show the indicator within the boundaries of, and therefore covered by, the article 12, thus creating a need for a translucent cover through which the indicator may be seen", as quoted above. The element identified by the reference numeral 12 is not the "article", but is the "diaper substrate", which comprises the inner layer 18, the absorbent layer 20, and the outer layer 22 (column 3, lines 1-2). The fluid transport layer 14 is either "disposed between the inner layer 18 and the absorbent layer 20...disposed between the absorbent layer 20 and the outer layer 22...[or]...incorporated with the inner layer 18 or the absorbent layer 20" (column 3, lines 24-30). In any of these configurations, it will appear in a plan view such as Figure 6 to be "within the boundaries" of the diaper substrate 12. However, as quoted above, the fluid transport layer 14 is "exposed along at least one or both of the opposite side portions 12E, 12F of the diaper substrate 12", such that "the visible response of the wetness indicator 16 can be visible along the at least one or both of the opposite side portions 12E, 12F of the peripheral edge 12A of the diaper substrate 12". Thus, as in the first and second embodiments, the disposition of the wetness indicator 16 in this third embodiment does not create a need for a translucent cover to enable the wetness indicator to be seen.

Finally, in a fourth embodiment shown in Figure 7, "the wetness indicator 16 is...exposed and extends...along a portion of the peripheral edge 12A" (column 4, line 66 through column 5, line 1; underlining added), and is therefore likewise visible along that edge. This embodiment was similarly mischaracterized in the Advisory Action, as quoted above, and the comments above with respect to the third embodiment are applicable to this embodiment, as well, with the qualification that the peripheral edge 12A where the wetness indicator 16 is exposed and visible in this embodiment is located at an end edge of the diaper, rather than at a side edge. Thus, the disposition of the wetness indicator 16 in this fourth embodiment likewise does not create a need for a translucent cover to enable the wetness indicator to be seen.

Thus, in every disclosed embodiment, without any modification, the wetness indicator of the Neading et al. reference may be easily viewed without removing the article and there is no need for a translucent cover to enable the indicator to be seen. Therefore, the stated motivation for combining the teachings of the references does not, in fact, exist.

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Furthermore, the Neading *et al.* reference explicitly teaches away from reapplying the structure taught by the cited Lee reference, to wit:

"prior art diaper wetness indicators are...disclosed in...U.S. Pat. No. 5,947,943 to Lee...The Lee patent, however, appears to be unduly complex and costly" (column 1, lines 28-30 and 45-46).

**This explicit consideration and rejection of the cited Lee reference in the Neading *et al.* reference is the direct obverse of a suggestion to modify its own teachings or to combine them with the teachings of the rejected Lee reference.**

**Summary with respect to rejections of Claims 3 and 13**

The cited references, either when taken alone or in combination, fail to teach or suggest all of the limitations of these claims. Additionally, the alleged suggestion or motivation to modify or to combine the teachings of the references as proposed does not exist and is contradicted by the explicit teaching of the Neading *et al.* reference, itself. Therefore, at least two of the three requirements for the establishment of a *prima facie* case of obviousness have not been met.

**SUMMARY OF THIS BRIEF**

The reference cited in the rejections under 35 USC § 102 fails to teach each and every element of any of the rejected claims. Therefore, the requirements for the anticipation rejections have not been met.

The references cited in the rejections under 35 USC § 103 fail to teach or suggest all of the limitations of the rejected claims. Additionally, the alleged suggestion or motivation to modify or to combine the teachings of the references as proposed does not exist and is contradicted by the explicit teaching of one of the references, itself. Therefore, the requirements for the establishment of a *prima facie* case of obviousness have not been met.

**Accordingly, it is respectfully requested that the rejections of the pending claims be reversed and that the subject Application be remanded with instructions that the pending claims be allowed over the cited references.**

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CLAIMS APPENDIX

CLAIMS ON APPEAL

1. A wearable article comprising:  
a topsheet adapted to fit about a portion of a wearer and receive urine discharged by the wearer; and  
a dehydration indicator disposed on and affixed to a component of the wearable article, the dehydration indicator being adapted to measure a urine ionic strength correlated to a specific gravity of the wearer's urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity.
2. The wearable article of Claim 1 wherein the dehydration indicator provides a qualitative indication of a urine specific gravity associated with dehydration.
3. The wearable article of Claim 1 further comprising a translucent cover covering the dehydration indicator.
4. The wearable article of Claim 1 wherein the dehydration indicator is affixed to the topsheet.
5. The wearable article of Claim 1 wherein the dehydration indicator comprises an indicium.
6. The wearable article of Claim 5 wherein the indicium serves as a color key for the dehydration indicator signal.
7. The wearable article of Claim 1 wherein the dehydration indicator is disposed on a carrier element.
8. The wearable article of Claim 1 wherein the dehydration indicator is covered by a semipermeable membrane.

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9. The wearable article of Claim 1 additionally comprising a fluid transport element in fluid communication with the dehydration indicator and serving to transport urine to the dehydration indicator.
10. A disposable absorbent article for receiving and containing bodily exudates including urine from a wearer, the disposable absorbent article comprising:  
an outer cover adapted to fit about a portion of the wearer;  
a fluid permeable topsheet onto and through which the urine is received;  
an absorbent structure disposed adjacent at least a portion of the outer cover; and  
a dehydration indicator adapted to measure a urine ionic strength correlated to a specific gravity of the wearer's urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity.
11. The disposable absorbent article of Claim 10 wherein the dehydration indicator is disposed on at least a portion of the topsheet.
12. The disposable absorbent article of Claim 11 wherein the dehydration indicator is detachable from the topsheet.
13. The disposable absorbent of Claim 10 further comprising a translucent cover covering the dehydration indicator.
14. The disposable absorbent article of Claim 10 wherein the dehydration indicator is covered by a semipermeable membrane.
15. The disposable absorbent article of Claim 10 wherein the dehydration indicator is disposed on a carrier element.
16. The disposable absorbent article of Claim 10 additionally comprising a fluid transport element in fluid communication with the dehydration indicator and serving to transport urine to the dehydration indicator.

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17. An insert for use with a wearable article, the insert comprising a dehydration indicator adapted to measure a urine ionic strength correlated to a specific gravity of a wearer's urine and provide a visible signal when the urine ionic strength reaches a value corresponding to a predetermined threshold of the specific gravity.
18. The insert of Claim 17 further comprising a topsheet onto and through which the wearer's urine is received, wherein the dehydration indicator is affixed to the topsheet.
19. The insert of Claim 17 wherein the dehydration indicator comprises an indicium.
20. The insert of Claim 19 wherein the indicium serves as a color key for the dehydration indicator signal.